



**[Billing Code 4140-01-P]**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of Exclusive License:** Development of Molecular-Based Cancer Diagnostic and Prognostic

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209 and 37 CFR 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to Heragen, Inc., which is located in Benicia, California to practice the inventions embodied in the following patent applications:

1. U.S. Provisional Application 61/152,597 filed February 13, 2009 entitled “Molecular-Based Method of Cancer Diagnosis and Prognosis” (HHS Ref No. E-023-2009/0-US-01).
2. International Application PCT/US2010/024026 filed February 12, 2010 entitled “Molecular-Based Method of Cancer Diagnosis and Prognosis” (HHS Ref No. E-023-2009/0-PCT-02).
3. U.S. Patent No. 8,715,928 issued May 6, 2014 entitled “Molecular-Based Method of Cancer Diagnosis and Prognosis” (HHS Ref No. E-023-2009/0-US-03).
4. U.S. Patent Application No. 14/215,574, filed March 17, 2014 entitled “Molecular-Based Method of Cancer Diagnosis and Prognosis” (HHS Ref No. E-023-2009/0-US-04).

The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of the Licensed Patent Rights to develop FDA approved and/or 510K cleared tests and kits for the diagnosis and prognosis of breast and lung cancer.

**DATES:** Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

**ADDRESSES:** Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Whitney A. Hastings, Ph.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 451-7337; Facsimile: (301) 402-0220; E-mail: [hastingw@mail.nih.gov](mailto:hastingw@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** Molecular profiling with high throughput assays has gained utility in the management of select cancer patients and several gene expression-based assays are now marketed for improved prognostic accuracy for patients with cancer.

This technology describes a genomics based diagnostic assay for the diagnosis and prognosis of cancer patients. Using a mouse model of breast cancer, the inventors identified a gene expression signature that can predict the outcome for human breast cancer patients with as few as six genes. The gene signature includes a total of 79 cancer survival factor-associated genes and was validated using available genomic test sets that were based on previously conducted human clinical trials. More recently, the six-gene-model was validated for cancers other than breast using multiple, independent, publicly-available human lung cancer data sets. In addition to predicting the outcome of cancer patients, this technology could also be used to stratify patients for further therapy and treat patients by administering therapeutic agents that alter the activity of one of the aforementioned cancer survival factor-associated genes.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license may be granted unless within thirty (30) days from the date of this published notice, the NIH receives

written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Any additional applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: July 9, 2014.

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Richard U. Rodriguez,  
Director,  
Division of Technology Development and Transfer,  
Office of Technology Transfer,  
National Institutes of Health.

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